

## **REMARKS**

### **I. Status**

Claims 1-15 are pending in the application.

Claims 1-3 are currently amended to further clarify the subject matter for which protection is sought, as discussed in greater detail below. All amendments herein are being made without prejudice to pursuing such subject matter in any continuing application, e.g., a continuation, divisional, request for continuation, etc. Support for the amendments can be found throughout the specification. No new matter is being added by the current amendments.

Claims 1-15 have been provisionally rejected under the doctrine of nonstatutory double patenting.

Claims 1-4, 6-8 and 11-15 stand rejected under 35 USC §112, ¶1 with regard to written description. Claims 1, 2 and 4-7 stand rejected under 35 USC §102(a) and (e) over U.S. Patent No. 6,232,304. Claims 3, 8 and 11-14 stand under 35 USC § 103(a) over U.S. Patent No. 6,232,304 and U.S. Patent No. 5,916,883. Applicants traverse the foregoing rejections.

### **II. Double Patenting Rejection is Overcome**

Claims 1-15 stand provisionally rejected under the non-obviousness type double patenting doctrine over claims 1-13 of U.S. Patent Application No. 10/693,307. Applicants traverse the rejection.

Nevertheless, to facilitate the allowance of the present application, Applicants are filing herewith a terminal disclaimer, which the Examiner states at page 2 of the Office Action can be used to overcome the present rejection. Thus, removal of the present rejection is appropriate.

### **III. Amended Claims 1-4, 6-8 and 11-15 Comply With the Written Description Requirements of §112, ¶1**

The standard for written description is whether a person skilled in the art would have recognized that the inventor was in possession of the invention as claimed at the time the application was filed.

While acknowledging that Applicants have identified functional groups of pharmaceutical compounds and functional polymers which are believed to be capable of ionic conjugation, the Examiner argues that the specification provides no guidance as to which pharmaceutical compounds and functional polymers could be used in the invention. Applicants respectfully disagree.

Contrary to the Examiner's contention, the instant specification does teach the characteristics of drug compounds sufficiently to indicate Applicants' possession of the invention. The specification describes preferred drug compounds as being insoluble or poorly soluble in water (e.g., page 2, lines 28-33) and insoluble in common organic solvents such as acetone, low molecular weight alcohols, hydrocarbons, diethyl ether and chlorocarbons. (see, pages 2, line 34 to page 3, line 7) . The specification provides a preferred embodiment of drug compounds that includes aryl-heterocyclic compounds such as the chlorooxyindole class, including those described in U.S. Patent No. 4,831,031 (see, page 3, lines 13-15).

Furthermore, the instant specification teaches the characteristics of functional polymers sufficiently to indicate Applicants' possession of the invention. The specification describes in general and in detail the types of polymers that would be functional polymers for the purposes of the invention. Functional polymers will bear moieties that provide suitable ionic attraction with the drug compounds (page 3, lines 21-32). Numerous exemplary polymers are described for ionic binding with basic drug compounds (page 3, line 33 to page 4, line 5 and page 4, line 26 to page 5, line 15) and drug compounds that are acidic such as sodium tenidap (page 4, lines 6-19).

Therefore, Applicants had possession of the claimed invention at the time the application was filed.

Nevertheless, to facilitate the allowance of the present application, Applicants are filing amendments to claims 1-3 to further define the invention based on the written description provided in the specification. Claim 1 now provides that pharmaceutical compounds are basic and poorly soluble in water and the functional polymer is a carboxyl bearing copolyester. Support for the amendments can be found throughout the specification, including at page 2, lines 28-31 and page 3, line 33 to page 4, line 2.

Based on the amendments to claims 1-3 and the arguments presented above, Applicants request reconsideration and withdraw of this rejection.

IV. **Amended Claims 1, 2 and 4-7 Are not Anticipated Under §102 By Kim**

Claims 1, 2 and 4-7 stand rejected under §102(a) and (e) over U.S. Patent 6,232,304 to Kim et al. Applicants submit that as amended, claims 1, 2 and 4-7 are not anticipated by Kim.

Applicants submit that there is no carboxyl moiety on the specific examples of cyclodextrins in Kim that can form an ionic bond with a basic poorly insoluble pharmaceutical compound. Also, the specific examples of cyclodextrins in Kim are not copolyesters. Therefore, Kim fails to disclose a functional polymer as claimed in the present invention.

Based on the amendments to the claims Applicants request reconsideration and withdraw of this rejection.

V. **Amended Claims 3, 8 and 11-14 are not Obvious over Kim and Shalaby**

Claims 3, 8 and 11-14 stand rejected under §103(a) over Kim and U.S. Patent 5,916,883 to Shalaby. Applicants traverse the rejection.

Amended claims 3, 8 and 11-14 generally are directed to solid ionic conjugates comprising a basic pharmaceutical compound and a functional polymer that is a carboxyl bearing copolyester, and processes for preparing the solid ionic conjugates.

Kim is directed to compositions of matter comprising a pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasidone in a cyclodextrin.

Shalaby is directed to a cyclodextrin derivative, wherein at least 60 percent of the free hydroxy groups of said cyclodextrin are acylated with acyl groups where at least one of said acyl groups comprise a free carboxylic group. The cyclodextrin derivatives disclosed Shalaby are functional polymers for some of the embodiments of the present invention.

Applicants submit, however, that no motivation exists to combine Kim and Shalaby in order to reach the present invention.

The Examiner bears the burden of establishing a prima facie case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (CAFC 1993).

It is error for the Examiner to reject a claimed invention as an obvious combination of the teachings of multiple prior art references when the prior art provided no teaching, suggestion or incentive supporting the combination. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990).

The Supreme Court recently reaffirmed its own earlier admonition against the dangers of hindsight bias stated in *Graham v. John Deere*, 383 US 1, 148 USPQ 459 (1966) to avoid the "temptation of reading into the prior art the teachings of the invention in issue". *KSR Int'l Co. v. Teleflex, Inc.*, 550 US 1, at 17 (2007).

The Supreme Court has described requirements for the possible applicability of an "obvious to try" test in determining whether a combination renders an invention obvious:

When there is a design need or market pressure to solve a problem ***and there are a finite number of identified predictable solutions***, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp...[T]he fact that a combination was obvious to try might show that it was obvious under §103. *KSR* at 17 (emphasis added).

While the inventors in Kim addressed the problem of poor solubility of ziprasidone, the disclosure in Shalaby solves a very different problem. Shalaby seeks to create sustained release compositions for use with highly soluble peptides.

Applicants submit that the problem solved by the present invention of increasing the solubility of a poorly soluble drug presents endless possibilities of alternative solutions. Such possibilities are not necessarily related to one another.

Furthermore, the problems that are sought to be solved in Kim and Shalaby are so different, and their methodologies so unrelated to each other that common sense requires they would not have been combined by one with ordinary skill in the art.

Applicants submit that the Examiner has failed to provide any teaching, suggestion or motivation in the prior art to support a combination of the relevant disclosure in the cited references. The Examiner has also failed to show how the cited references, either individually or in combination with each other, would motivate one of ordinary skill in the art to practice the invention. Furthermore, given the infinite number of possible solutions for solving the problem of poorly soluble drug compounds, it would be error and is beyond common sense to expect that practitioners with ordinary skill in the art would be motivated to combine the Shalaby and Kim references.

Based on the amendments to the claims and the arguments presented above, Applicants request reconsideration and withdraw of this rejection.

VI. **Conclusion**

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of the single pending claim at this time. To the extent the Examiner believes it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe a fee is associated with the present filing, which is detailed in form PTO/SB/17 filed herewith. To the extent any additional fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 16-1445.

Respectfully submitted,

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/Gabriel Kleiman/  
Gabriel L. Kleiman  
Attorney for the Applicants  
Reg. No. 40,681

Pfizer Inc.  
Pfizer Inc.  
Patent Department  
150 East 42nd Street  
Mail Stop: 150/05/49  
New York, New York 10017  
Phone: 212-733-0803